REMARKS

In the aforesaid Office Action, claims 26 and 28-37 were rejected under 35 USC 112, first paragraph, claims 26, 28-29, 34 and 35 were rejected under 35 USC 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending.

The Examiner rejected claims 26 and 28-37 under 35 USC 112, first paragraph, stating, in part, that there is insufficient disclosure in the specification to support the assertion that the outer diameter of the balloon at nominal inflated pressure is less than the inner diameter of the balloon mold. For support for claim 26 requiring that the balloon has a radial shrinkage of greater than 0%, the Examiner's attention is directed to paragraph [0032] of Applicant's specification, which discloses an embodiment in which the balloon affirmatively has a radial shrinkage or a measurable change in the outer diameter, i.e., "the formed balloon has a minimal radial shrinkage (for example, as measured by the % change in the outer diameter of the working length of an inflated balloon as part of a catheter system versus as formed after the present process)." Applicants are not required to use in the claims a verbatim phrasing of the disclosure of the application as filed. The above quoted disclosure of a balloon which affirmatively has **a** radial shrinkage can be rephrased to set forth a balloon which has a radial shrinkage of greater than 0%. As a result, claim 26 is fully supported by the disclosure of Applicant's application as filed.

Applicants have amended claim 26 to set forth that the radial shrinkage is measured by a difference between the "inflated outer diameter of the balloon at a substantially ambient temperature in the balloon mold used to blow-mold the balloon and the inflated outer diameter of the balloon at an inflation pressure required to fill the blow-molded inflated volume at ambient temperature as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage", and that the balloon forming process includes cooling the inflated balloon to substantially ambient temperature within the mold after the heat-setting. Support for the amendment to claim 26 can be found at paragraph [0034] disclosing that a balloon forming process includes cooling the balloon in the mold under pressure, and paragraph [0032] disclosing that the radial shrinkage is measured by the % change in the outer diameter of the working length of an inflated balloon as part of a catheter system, versus as formed after the present process.

The Examiner rejected the claims based on Wang et al., stating in the Response to Arguments section of the aforesaid Office Action that without support in the written specification that the outer diameter of the claimed balloon at a nominal inflated pressure is less than the inner diameter of the balloon mold, claim 26 is not clearly defined over Wang et al. However, as set forth above, the claim 26 is fully supported by the disclosure of Applicant's application as filed.

The Examiner further states in the Response to Arguments section that because there is a shrinkage of the Wang et al. balloon due to the decrease in temperature (Tm-Ta), the inflated balloon at a nominal pressure must have a shrinkage in the outer

diameter as asserted by the Applicant. However, Applicant's claim 26 requires that the radial shrinkage is measured by a difference between the inflated outer diameter of the balloon at substantially ambient temperature in the balloon mold used to blow-mold the balloon and the inflated outer diameter of the balloon at an inflation pressure required to fill the blow-molded inflated volume at ambient temperature as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage. Therefore, the radial shrinkage in the outer diameter required by claim 26 cannot be merely due to the cooling of the balloon from the elevated blow-molding temperature. Rather, the percent radial shrinkage is based on the inflated outer diameter of the balloon in the balloon mold after it is cooled while pressurized.

The Examiner has provided no rational for the assertion that there must be a positive shrinkage percentage of the outer diameter of the balloon of Wang et al. due to the decrease in temperature to ambient (Ta) from the elevated temperature used to blow mold the balloon (Tm). Rather, the Examiner contradictorily also asserts that in Wang et al., the inflated outer diameter of the balloon is equal to the inner diameter of the balloon mold/nominal outside diameter of the balloon at ambient temperature (2.25mm in example 1; 3mm in example 2), as Wang et al. explicitly discloses at col. 6, lines 30-36 that a 3.0 mm size mold was used to produce a 3.0 mm balloon.

Moreover, Applicant's claim 26 requires that the balloon (heat set using a heating member applying heat simultaneously along the length of the balloon) has an inflated outer diameter radial shrinkage is less than that of a balloon heat-set nonuniformly, which would not appear to be the case for a radial shrinkage of the inflated outer diameter

envisioned by the Examiner as being due merely to cooling the balloon from the elevated temperature used during balloon formation.

Regarding the repeated rejection of the claims based on Wang et al., the Examiner states that Wang et al. discloses balloons (examples 1-2) having radial distention % or shrinkage % less than 10% as measured by a difference from the inflated outer diameters of the balloons/nominal diameters (2.25mm in example 1; 3mm in example 2) and the inner diameters of the molds/nominal outside diameters of the balloons at ambient temperature (2.25mm in example 1; 3mm in example 2), when inflated to a nominal pressure (88 psi/6 atm). The Examiner further states that a claimed product cannot be patentable over another product having the same structure limitations even though the two products are created by different processes, and that there in no substantial difference in the structural limitations between the claimed balloon and the balloon disclosed by Wang '383.

However, the outer diameter of the balloon is a physical attribute of the balloon, and thus is a structural limitation. Specifically, Applicant's claim 26 requires that the balloon has an outer diameter when inflated at the nominal pressure after a shrinking treatment which is less than the inflated outer diameter of the balloon at a substantially ambient temperature in the balloon mold (i.e., the nominal outer diameter of the balloon before the shrinking treatment) by an amount which is greater than 0% but less than 10%. In contrast, as set forth by the Examiner, Wang discloses a balloon having an outer diameter when similarly inflated to the nominal pressure which is equal to the inner diameter of the balloon mold/nominal outside diameters of the balloons at ambient

temperature. Thus, irrespective of the process used to form the balloons, Applicant's claim 26 requires that the inflated outer diameter radial shrinkage is greater than 0% but less than 10% (i.e., at the nominal inflation pressure, the balloon inflated outer diameter after the shrinking treatment is less than the balloon inflated outer diameter before the shrinking treatment by an amount which is greater than 0% but less than 10%).

The Examiner states that in addition, Wang (at col. 1, lines 41-45) discloses "non-compliant" balloons which are least elastic having a diameter change in a range of 2%-7% as the balloons are pressurized from a pressure from 6-12 atm, and thus it is clear that the well-known inelastic balloon are very dimensional stable and meet the requirement of the balloon as recited in the claims.

However, the disclosure of Wang referred to by the Examiner relates to the growth of the balloon as the inflation pressure is increased to pressures above the nominal inflation pressure. In contrast, Applicant's claim 26 requires dimensional stability at the nominal pressure, as discussed above. Therefore, although Wang does disclose non-compliant balloons which have a limited 2-7% diameter increase as the balloons are pressurized above nominal (e.g., above 6 atm), Wang does not disclose or suggest a balloon having a radial shrinkage of less than 10% but greater than 0% as required by Applicant's claim 26.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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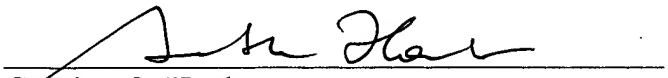
By: 

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